APR - 7 2004

K033866

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085
Phone: (408) 732-3856
Fax: (408) 732-3849

Contact: Cheng-I Lin, Ph.D.
President, R&D Director

Device Name and Classification

1. Classification Name: Cocaine Metabolite, Amphetamines, Opiate, and Phencyclidine test system,

   The Cocaine and Cocaine Metabolite test system has been placed in Class II by the Bureau of Medical Devices.
   Classification Number: DIO (21 CFR 862.3250)
   Panel: 91 Toxicology

   The Amphetamine test system has been placed in Class II by the Bureau of Medical Devices.
   Classification Number: DKZ (21 CFR 862.3100)
   Panel: 91 Toxicology

   The Opiate test system has been placed in Class II by the Bureau of Medical Devices.
   Classification Number: DJG (21 CFR 862.3650)
   Panel: 91 Toxicology

   The Phencyclidine test system
   Classification Number: LCM
   Panel: 91 Toxicology

Common Name:	Homogeneous enzyme immunoassay for the detection of cocaine metabolite, amphetamines, opiate, and phencyclidine in human urine.
Proprietary Name:	CAMP Enzyme Immunoassay

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.'s Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay is substantially equivalent to Cocaine Metabolite Enzyme Immunoassay, Amphetamines Enzyme Immunoassay, Opiate Enzyme Immunoassay, and Phencyclidine Enzyme Immunoassay by Lin-Zhi International, Inc., cleared under premarket notification K020763 (Cocaine Metabolite Enzyme Immunoassay), K020369 (Amphetamines Enzyme Immunoassay), K020368 (Opiate Enzyme Immunoassay), and K020254 (Phencyclidine Enzyme Immunoassay).

LZI's Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay is similar to their predicates in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect cocaine metabolite, amphetamines, opiate and phencyclidine in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on competition between drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free drug from the urine sample for a fixed amount of specific antibody. In the absence of free drug from the urine sample the specific antibody binds to the drug labeled G6PDH enzyme causing a decrease in enzyme activity. It is therefore the drug concentration is proportional to the enzyme activity. The G6PDH enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to covert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use

The Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay (CAMP) is a homogeneous enzyme immunoassay with 300 ng/mL cutoff for cocaine metabolite, 1000 ng/mL cutoff for methamphetamine, 300 ng/mL cutoff for opiate, and 25 ng/mL cutoff for phencyclidine. The assay is solely intended for use in the qualitative screening for negative human urine samples for cocaine metabolite, amphetamines, opiate, and phencyclidine drugs.

Comparison to Predicate Device

LZI's Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay (CAMP) is substantially equivalent to the individual single analyte assay products in commercially distribution intended for similar use. Most notably it is substantially equivalent to the Cocaine Metabolite Enzyme Immunoassay, Amphetamines Enzyme Immunoassay, Opiate Enzyme Immunoassay, and Phencyclidine Enzyme Immunoassay By Lin-Zhi International, Inc., cleared under premarket notification K020763 (Cocaine Metabolite Enzyme Immunoassay), K020369 (Amphetamines Enzyme Immunoassay), K020368 (Opiate Enzyme Immunoassay), and K020254 (Phencyclidine Enzyme Immunoassay).

The following table compares LZI's Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay (CAMP) with the predicate devices, Cocaine Metabolite Enzyme Immunoassay, Amphetamines Enzyme Immunoassay, Opiate Enzyme Immunoassay, and Phencyclidine Enzyme Immunoassay by Lin-Zhi International, Inc.

Similarities:

- Both assays are used for qualitative detection of drug in human urine.
- Both have same cutoff design (300 ng/mL for cocaine metabolite, 1000 ng/mL for methamphetamine, 300 ng/mL for opiate, and 25 ng/mL for phencyclidine).
- Both assays use same control concentration (+/- 25% of cut-off value).
- Both assays use the same method principle, and device components.

Difference:

- Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay is designed for qualitative screening purpose only.
- Multiple analyte calibrators/controls cannot be use in this assay.
- The CAMP assay should be calibrated with Opiate calibrators only.

Performance Characteristics

Feature	LZI's CAMP EIA				LZI's Cocaine Metabolite EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	736.3	5.5	0.75	Negative	243.7	0.9	0.37
	225 ng/mL	786.2	5.1	0.65	225 ng/mL	356.8	1.8	0.50
	300 ng/mL	803.6	7.7	0.96	300 ng/mL	380.2	1.8	0.48
	375 ng/mL	811.9	7.0	0.86	375 ng/mL	397.3	2.2	0.56
	3000 ng/mL	876.8	5.3	0.61	3000 ng/mL	488.4	1.8	0.36
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	742.4	3.5	0.48	Negative	243.1	0.9	0.36
	225 ng/mL	793.4	5.1	0.65	225 ng/mL	354.8	2.4	0.67
	300 ng/mL	806.9	4.4	0.55	300 ng/mL	377.0	3.5	0.93
	375 ng/mL	822.1	7.0	0.85	375 ng/mL	394.6	2.1	0.53
	3000 ng/mL	882.3	5.5	0.62	3000 ng/mL	486.0	2.4	0.49
Sensitivity:	50 ng/mL				4 ng/mL			
Accuracy:	Vs. LZI Cocaine metabolite EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				100 % agreement			
Negative Samples:	100% agreement				100 % agreement			
Analytical Recovery:	100 % agreement on positive vs. negative tests				100 % agreement on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Feature	LZI's CAMP EIA				LZI's Amphetamines EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	734.7	6.2	0.85	Negative	273.0	1.0	0.35
	750 ng/mL	793.0	6.4	0.81	750 ng/mL	390.0	1.4	0.37
	1000 ng/mL	804.0	4.9	0.60	1000 ng/mL	415.7	1.4	0.34
	1250 ng/mL	810.2	5.9	0.73	1250 ng/mL	439.0	1.6	0.37
	2000 ng/mL	825.5	5.7	0.69	2000 ng/mL	480.5	1.4	0.30
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	742.4	3.5	0.48	Negative	272.9	2.3	0.8
	750 ng/mL	792.8	4.3	0.54	750 ng/mL	390.5	2.9	0.7
	1000 ng/mL	799.0	3.8	0.47	1000 ng/mL	415.9	3.0	0.5
	1250 ng/mL	808.9	6.1	0.76	1250 ng/mL	439.1	3.6	0.4
	2000 ng/mL	828.4	3.3	0.40	2000 ng/mL	479.6	3.5	0.4
Sensitivity:	100 ng/mL				30 ng/mL			
Accuracy:	Vs. LZI Amphetamines EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				100 % agreement (100% vs. GC/MS /HPLC)			
Negative Samples:	100 % agreement				100 % agreement			
Analytical Recovery:	100 % agreement on positive vs. negative tests				100 % agreement on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Feature	LZI's CAMP EIA				LZI's Opiate EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	736.0	6.6	0.90	Negative	291.6	2.19	0.75
	225 ng/mL	782.4	7.2	0.92	225 ng/mL	374.4	3.01	0.80
	300 ng/mL	801.8	7.4	0.92	300 ng/mL	399.8	3.42	0.86
	375 ng/mL	817.5	6.4	0.78	375 ng/mL	421.8	3.20	0.76
	1000 ng/mL	878.7	5.9	0.67	1000 ng/mL	530.8	5.17	0.97
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	742.4	3.5	0.489	Negative	292.8	1.81	0.62
	225 ng/mL	793.0	6.5	0.81	225 ng/mL	375.8	3.61	0.96
	300 ng/mL	809.1	4.6	0.01	300 ng/mL	400.8	3.34	0.83
	375 ng/mL	819.8	3.1	0.37	375 ng/mL	421.1	2.87	0.68
	1000 ng/mL	886.0	6.2	0.69	1000 ng/mL	528.6	4.84	0.92
Sensitivity:	50 ng/mL				15 ng/mL			
Accuracy:	Vs. LZI Opiate EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				97.1 % agreement(100% vs. GC/MS /HPLC)			
Negative Samples:	100 % agreement				93.8 % agreement			
Analytical Recovery:	100 % agreement on positive vs. negative tests				100 % agreement on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Feature	LZI's CAMP EIA				LZI's Phencyclidine EIA			
Within Run Precision:	(mA/min.)	Mean.	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=21)	Negative	735.1	6.2	0.84	Negative	168.0	0.68	0.41
	18 ng/mL	789.6	6.2	0.78	18 ng/mL	238.6	1.16	0.49
	25 ng/mL	799.2	5.2	0.66	25 ng/mL	264.6	1.19	0.45
	32 ng/mL	809.3	7.0	0.87	32 ng/mL	282.8	1.42	0.50
	100 ng/mL	833.5	6.3	0.76	100 ng/mL	341.2	0.73	0.21
Run-To-Run Precision:	(mA/min.)	Mean	SD	% CV	(mA/min.)	Mean	SD	% CV
(n=12)	Negative	742.4	3.4	0.48	Negative	168.0	0.90	0.54
	18 ng/mL	794.1	5.0	0.63	18 ng/mL	238.8	0.55	0.23
	25 ng/mL	804.9	5.1	0.63	25 ng/mL	264.6	0.79	0.30
	32 ng/mL	814.0	4.6	0.57	32 ng/mL	284.1	0.87	0.31
	100 ng/mL	829.1	4.7	0.56	100 ng/mL	340.1	1.07	0.32
Sensitivity:	3 ng/mL				1 ng/mL			
Accuracy:	Vs. LZI Phencyclidine EIA				Vs. a commercial EIA			
Positive Samples:	100 % agreement				100 % agreement(100% vs. GC/MS /HPLC)			
Negative Samples:	100 % agreement				100 % agreement			
Analytical Recovery:	100 % agreement on positive vs. negative tests				100 % agreement on positive vs. negative tests			
Specificity:	See attached Assay package insert				Comparable to the predicate device.			

Conclusion

The LZI's Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay was evaluated for several performance characteristics including precision, sensitivity, accuracy, analytical recovery, and specificity. All the studies showed acceptable results when compared to the individual predicate device.

We trust the information provided in this Premarket Notification [510(k)] submission will support a determination of substantial equivalence of the LZI's Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay to other individual test systems for screening purpose currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 7 2004

Cheng-I Lin, Ph.D.
President, R&D Director
Lin-Zhi International, Inc.
687 North Pastoria Avenue
Sunnyvale, CA 94085

Re: k033866
Trade/Device Name: Simultaneous Cocaine- Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO, DJG, DZK, LCM
Dated: March 19, 2004
Received: March 23, 2004

Dear Dr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Premarket Notification

Indications for Use

510(k) Number (if known): K033866

Device Name: Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay

Indications for Use:

The Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay is a homogeneous enzyme immunoassay with 300 ng/mL cutoff for cocaine metabolite, 1000 ng/mL cutoff for amphetamines, 300 ng/mL cutoff for opiates, and 25 ng/mL cutoff for phencyclidine. The assay will produce a positive result if any of the four analyte are present at a concentration at or above their respective cutoffs but will not identify which drug is present. The assay is solely intended for the qualitative screening of human urine for these analytes. Measurements obtained by this device are used in the diagnosis and treatment of individuals who have used cocaine, amphetamines, opiates, or phencyclidine. The assay is designed for professional use with a number of automated clinical chemistry analyzers.

The Simultaneous Cocaine-Amphetamines-Morphine-Phencyclidine Multiple Analyte Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method for the individual drugs must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K033866

Prescription Use V **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)